

§ 152.42

§ 152.42 Application for new registration.

Any person seeking to obtain a registration for a new pesticide product must submit an application for registration, containing the information specified in § 152.50. An application for new registration must be approved by the Agency before the product may legally be distributed or sold, except as provided by § 152.30.

§ 152.43 Alternate formulations.

(a) A product proposed for registration must have a single, defined composition, except that EPA may approve a basic formulation and one or more alternate formulations for a single product.

(b) An alternate formulation must meet the criteria listed in paragraph (b) (1) through (4) of this section. The Agency may require the submission of data to determine whether the criteria have been met.

(1) The alternate formulation must have the same certified limits for each active ingredient as the basic formulation.

(2) If the alternate formulation contains an inert ingredient or impurity of toxicological significance, the formulation must have the same upper certified limit for that substance as the basic formulation;

(3) The label text of the alternate formulation product must be identical to that of the basic formulation.

(4) The analytical method required under § 158.180 must be suitable for use on both the basic formulation and the alternate formulation.

(c) Notwithstanding the criteria in this section, the Agency may determine that an alternate formulation must be separately registered. If EPA makes this determination, the Agency will notify the applicant of its determination and its reasons. Thereafter the application for an alternate formulation will be treated as an application for new registration, and the alternate formulation will be assigned a new registration number.

§ 152.44 Application for amended registration.

(a) Except as provided by § 152.46, any modification in the composition, label-

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ing, or packaging of a registered product must be submitted with an application for amended registration. The applicant must submit the information required by § 152.50, as applicable to the change requested. If an application for amended registration is required, the application must be approved by the Agency before the product, as modified, may legally be distributed or sold.

(b) In its discretion, the Agency may:

(1) Waive the requirement for submission of an application for amended registration;

(2) Require that the applicant certify to the Agency that he has complied with an Agency directive rather than submit an application for amended registration; or

(3) Permit an applicant to modify a registration by notification or non-notification in accordance with § 152.46.

(c) A registrant may at any time submit identical minor labeling amendments affecting a number of products as a single application if no data are required for EPA to approve the amendment (for example, a change in the wording of a storage statement for designated residential use products). A consolidated application must clearly identify the labeling modification(s) to be made (which must be identical for all products included in the application), list the registration number of each product for which the modification is requested, and provide required supporting materials (for example, labeling) for each affected product.

[53 FR 15978, May 4, 1988, as amended at 61 FR 33041, June 26, 1996; 66 FR 64764, Dec. 14, 2001]

§ 152.46 Notification and non-notification changes to registrations.

(a) *Changes permitted by notification.*

(1) EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished by notification to the Agency, without requiring that the registrant obtain Agency approval. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of modifications permitted by notification and any conditions and procedures for submitting notifications.